

Applicants: Omry Ben-Ezra, et al.

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Remarks

This application contains claims 1-364, the status of which is as follows:

- (a) Claims 21, 23, 25, 30-38, 40-41, 43-45, 164, 166, 168, 173-181, 183-184, and 186-188 have been currently amended.
- (b) Claims 22, 24, 39, 42, and 185 were previously presented.
- (c) Claims 165, 167, and 182 are as originally filed.
- (d) Claims 1-20, 26, 46-163, 169, and 189-360 were previously canceled.
- (e) Claims 27-29 and 170-172 have been currently canceled without prejudice.
- (f) Claims 361-364 are new.

No new matter has been added.

Applicants thank Examiners Dietrich and Evanisko for the courtesy of a personal interview with Applicants' representative, Sanford T. Colb (Reg. No. 26,856), held in the USPTO on July 29, 2008. At the interview, Mr. Colb proposed amendments to overcome the rejections of independent claims 21 and 164 under U.S.C. 112, and argued the patentability of these claims as amended under 35 U.S.C. 102(b). The Examiners agreed that replacing the phrase "without terminating the occurrence of the AF" with the phrase "while the atrial cells typically remain unsynchronized" overcomes the rejections under U.S.C. 112, and that the claims thus amended would appear to read over the art of record. The Examiners indicated that further search and closer reading of the prior art is necessary.

***Claim rejections under 35 U.S.C. 112***

Claims 21-25, 27-45, 164-168, and 170-188 were rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner argued that the phrase "without terminating the occurrence of AF," which was added by previous amendment to claims 21 and 164, is not adequately described in the specification. While not necessarily agreeing with this rejection, Applicants have amended independent claims 21 and 164 to remove this phrase, thereby obviating the rejection.

***Claim rejections under 35 U.S.C. 102 and 103***

Claims 21, 23, 25, 27, 28, 164, 166, 168, 170, and 171 were rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,928,269 to Alt. The Examiner argued that "Because Alt delivers pulses to the patient in a way that alternates between a "low" stimulation and a "high" stimulation, it is apparent that Alt would also be capable of increasing atrial motion without terminating the occurrence of the atrial fibrillation" (#5, emphasis in original).

Claims 22, 24, 29, 30, 31, 165, 167, 172, 173, and 174 were rejected under 35 U.S.C. 103(a) as being unpatentable over Alt and further in view of US Patent Application Publication 2003/0045909 to Gross et al. Claims 26 and 169 were rejected under 35 U.S.C. 103(a) as being unpatentable over Alt and further in view of US Patent 7,079,891 to Kroll. Claims 29, 32, 35-37, 39, 42, 43, 172, 175, 178-180, 182, 185, and 186 were rejected under 35 U.S.C. 103(a) as being unpatentable over Alt and further in view of US Patent 6,341,236 to Osorio et al. Claims 44, 45, 187, and 188 were rejected under 35 U.S.C. 103(a) as being unpatentable over Alt and further in view of Osorio et al.

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Claims 33, 34, 38, 176, 177, and 189 were rejected under 35 U.S.C. 103(a) as being unpatentable over Alt in view of Osorio, and further in view of Gross et al. Claims 40, 41, 183, and 184 were rejected under 35 U.S.C. 103(a) as being unpatentable over Alt in view of Osorio, and further in view of US Patent 6,256,537 to Stoop et al.

Applicants have amended independent claims 21 and 164 to include the features of rejected dependent claims 29 and 172, namely the application of the current to the vagus nerve, and have accordingly canceled claims 29 and 172. Applicants respectfully disagree with the rejection of these dependent claims.

Although the Examiner admitted that Alt does not teach applying the current to the vagus nerve, the Examiner argued that it would be obvious to combine Alt's defibrillation techniques with the vagus nerve stimulation techniques of Gross et al. or Osorio et al.: "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify electrode and stimulation as taught by Alt with the electrode coupled to the vagus nerve for stimulation of the vagus nerve as taught by Gross, since such a modification would provide the predictable results of treating heart conditions" (pp. 6-7 of the office action, regarding Gross; the Examiner made similar arguments regarding the combination of Alt with Osorio et al. on p. 9 of the office action).

Applicants respectfully submit that the Examiner has failed to make a *prima facie* case for combining Alt with either Gross et al. or Osorio et al. Claims 21 and 164, as currently amended, recite (and rejected dependent claims 29 and 172 recited) vagus

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nerve stimulation, while Alt describes stimulation of cardiac tissue. Even if it were the case that Alt's application of "electrical shocks of variable energy content sufficient for cardioverting atrial fibrillation" (claim 9 of Alt) increases atrial motion, as argued by the Examiner, it would not be "predictable" that substituting vagal stimulation for cardiac tissue stimulation would have the same cardioversion effect. The Examiner has not made any arguments that one of ordinary skill in the cardioversion art would even consider trying the vagus nerve stimulation of Gross et al. or Osorio et al. in combination with Alt's techniques for atrial cardioversion. As is well known, the vagus nerve is parasympathetic, such that stimulation thereof generally has the effect of reducing cardiac activity. In contrast, Alt describes the application of defibrillating electrical shocks "to reset the fibrillating atrial cells so as to terminate the atrial fibrillation and convert it to sinus rhythm" (col. 3, lines 13-15). One of ordinary skill in the art would not have a reasonable expectation that stimulation of the vagus nerve instead of cardiac tissue would perform atrial cardioversion, as taught by Alt.

Applicants therefore respectfully submit that claims 21 and 164 are in a condition for allowance. All of the other claims that remain pending in the application are also in a condition for allowance, because they directly or indirectly depend from allowable independent claims 21 and 164.

***Other claim amendments and new claims***

Claims 32 and 175 have been amended to recite that the stimulation cycles between first and second stimulation periods.

Conforming amendments have been made to claims 33-38, 40-41, 43-45, 176-181, 183-184, and 186-188. These amendments are

supported in the specification as filed: "Typically, the control unit configures the stimulation to cycle continuously between 'high' and 'low' stimulation when applying the treatment" (p. 54, lines 11-12).

As mentioned above, dependent claims 32 and 175 were rejected under 35 U.S.C. 103(a) as being unpatentable over Alt and further in view of Osorio et al. Applicants respectfully submit that claims 32 and 175, as currently amended, would be patentable even if independent claims 21 and 164 were found to not be allowable.

Applicants respectfully submit that Osorio et al. does not teach the features of claims 32 and 175, including cycling between two periods. The passage the Examiner cited from Osorio et al. reads: "Another option is to automatically turn off the stimulation provided to the vagus nerve 60. A third option is to adjust the stimulation by adjusting the pulse frequency, amplitude, and/or width (discussed further herein)" (col. 10, lines 16-20). At the beginning of the paragraph, Osorio et al. explain the purpose of these techniques: "At step 625, if it is determined that the vagus nerve stimulation needs to be adjusted, any number of approaches may be taken" (col. 10, lines 10-12). These techniques for adjusting vagus nerve stimulation do not involve cycling between two periods.

Furthermore, there would be no motivation or reason for one of ordinary skill in the art to combine the nerve stimulation techniques of Osorio et al. with the cardiac tissue cardioversion techniques of Alt. Osorio et al. teach techniques "for using electrical stimulation of the vagus nerve to treat epilepsy with minimized or no effect on the heart" (abstract, emphasis added). Osorio et al. teach away from a combination with Alt, because

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the goal of Osorio et al. is to treat epilepsy without affecting the heart, while the goal of Alt is to cardiovert the fibrillating heart.

Claims 30-32 have been amended to depend from claim 21, rather than canceled claim 29. Claims 173-175 have been amended to depend from claim 164, rather than canceled claim 172. Claims 23, 25, 166, and 168 have been amended to update antecedent basis in light of the amendments to independent claims 21 and 164, respectively. The last clause in claims 23, and claim 166 have been restored to the language of the claims as originally filed (except for the addition of the word "further" in claim 166).

Claims 361 and 362 are new, and are supported *inter alia* in the application as filed as follows: "In an embodiment, the electrode device is adapted to be coupled to the tissue of the subject, the subject suffering from atrial fibrillation (AF) or from increased risk of thromboembolic events" (p. 21, lines 29-31). This sentence appears in the context of the embodiment of the invention recited in claims 21 and 164, as described on p. 21, lines 20-26. Furthermore, claim 166 as originally filed read: "A method according to claim 164, comprising identifying that the subject is suffering from atrial fibrillation (AF) or from increased risk of thromboembolic events."

Claims 363 and 364 are new, and are supported *inter alia* in the application as filed as follows:

In an embodiment of the present invention, control unit 32 drives electrode device 22 to apply signals to vagus nerve 24, and configures the signals so as to increase atrial motion. . . . In an

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embodiment, control unit 32 modulates the vagal stimulation as follows:

- during a "high" stimulation period, . . . , the control unit configures the vagal stimulation so as to cause a reduction in the force of contraction of atrial cells; and
- during a "low" stimulation period, . . . , the control unit configures the vagal stimulation so as to cause the atrial cells to contract with "rebound" strength (although, because of the AF, the atrial cells typically remain unsynchronized during this rebound contraction) (p. 53, lines 13-28).

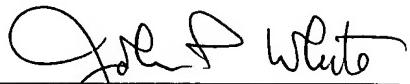
Applicants believe the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection raised by the Examiner. In view of these amendments and remarks, Applicants respectfully submit that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee, other than the \$65.00 fee for a one (1) month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

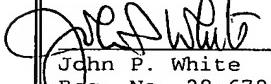
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Date